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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/828,795

04/21/2004

Eckard Weber

OREX.001A

5046

20995

7590

08/24/2006

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EXAMINER

ZHANG, NANCY L

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/828,795	<b>Applicant(s)</b> WEBER ET AL.	
	<b>Examiner</b> Nancy L. Zhang	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 8-11, 19 and 22-37 is/are pending in the application.  
     4a) Of the above claim(s) 10, 11, 19 and 22-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8, 9, 36 and 37 is/are rejected.
- 7) ☒ Claim(s) 8 and 36 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3 sheets, 6/24/05, 9/2/05</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's election without traverse of Group (I), claims 8-9 and 36-37 in the reply filed on 08/08/2006 is acknowledged. Applicant's election for a single disclosed species of a composition comprising naltrexone as the 1<sup>st</sup> component and bupropion as the 2<sup>nd</sup> component is also acknowledged.

Claims 10-11, 19 and 22-35 are withdrawn from consideration because they are not directed to the elected invention.

Claims 8-9 and 36-37 are examined.

### ***Claim Objections***

Claims 8 and 36 are objected to because of the following informalities: the claims include the species **prodrug** which is not directed to the elected species. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-9 and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Dante (US Patent 5,817,665, issue date Oct. 6, 1998).

Claims 8-9 recite a composition for affecting weight loss comprising a 1<sup>st</sup> compound and a 2<sup>nd</sup> compound wherein the 1<sup>st</sup> compound is naltrexone and the 2<sup>nd</sup> compound is bupropion. Claims 36-37 recite a pharmaceutically composition comprising a 1<sup>st</sup> compound and a 2<sup>nd</sup> compound wherein the 1<sup>st</sup> compound is naltrexone and the 2<sup>nd</sup> compound is bupropion.

Dante discloses a composition for treating depression comprising a pharmacologically effective dose of a compound of opioid antagonists and a pharmacologically effective dose of a compound of nontricyclic antidepressants (column 8, claim 9). The opioid antagonist can be naltrexone (claim 9, line 5) and the nontricyclic antidepressant can be bupropion (claim 12, line 4). Therefore, a composition or a pharmaceutical composition of naltrexone and bupropion is clearly anticipated. The composition disclosed by Dante meets all the limitations set forth in claims of the instant application.

The affecting weight loss in the preambles of claims 8-9 is intended use of the composition. The composition of the instant application is identical to the composition used by Dante. The preamble of the claims merely recites a different intended use of the composition and as such does not limit the claims. *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F. 3d 801,808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002). “[T]he recitation of a new intended use for an old product does not make a claim to that old product patentable.” *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997).

Therefore, claims 8-9 and 36-37 are clearly anticipated.

***IDS***

The information disclosure statement filed on September 02, 2005 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because reference No. 7 cites an International Preliminary Examination Report. An International Search Report is not a published document. It has been placed in the application file, but the information referred to therein has not been considered as to the merits.

***Conclusion***

No claimed are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy L. Zhang whose telephone number is (571)-272-8270. The examiner can normally be reached on Mon.- Fri. 8:30am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*nlm 8/17/06*

NLZ

*Ardin H. Marschel 8/18/06*  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER